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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------------|---------------------|------------------|
| 09/554,533 | 07/11/2002 | Nigel Robert Arnold Beeley | 238/086 PCT/US | 1938 |

44638 7590 10/03/2005
ARNOLD & PORTER LLP (18528)
555 TWELFTH ST, NW
WASHINGTON, DC 20004

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| EXAMINER |
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UNGAR, SUSAN NMN

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,533

Applicant(s)

BEELEY ET AL

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 May 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group 1. Claim 1-in-part is drawn to the peptide compound, His, Ser, Asp, Gly, Ala, Ala, Thr, Ala, Asp, Leu, Ser, Lys, Gln, Leu, Glu, Glu, Glu, Ala, Val, Arg, Leu, Phe, Ile, Glu, Trp, Leu, Lys, Asn, -OH which is the first invention first mentioned in the claim. Claims 2-30 will be examined as they are drawn to a method of treating diabetes mellitus comprising administering a therapeutically effective amount of said peptide.

Group 2. Claim 1-in-part is drawn to a plethora of peptide compounds comprising a Gly at position 4 and Ala at position 18, other than the peptide compound invention first mentioned in claim 1, wherein the other amino residues of the peptide are drawn from various combinations of amino acids defined in claim 1, each specific combination of amino acid residues being a special technical feature that is distinct from the other combinations. Claims 2-22, will be examined only as they are drawn to the specific peptide elected for examination. It is noted for Applicant's convenience that this is not a requirement for an election of species but rather a requirement to elect a specific peptide sequence for examination. Applicant is required to identify and elect a single method for examination.

Group 3. Claims 23-30 are drawn to a plethora of methods of treatment of diabetes mellitus comprising administering a peptide compound, other than the peptide compound invention first mentioned in claim 1, wherein said peptide compound comprises a Gly at position 4 and Ala at position 18 wherein the other amino acid residues of the peptide are drawn from various combinations of amino acids defined in claim 1, each

method being a special technical feature that is distinct from the other methods. It is noted for Applicant's convenience that this is not a requirement for an election of species but rather a requirement to elect a specific method of treatment for examination. Applicant is required to identify and elect a single method for examination.

Group 4. Claims 31 are drawn to a plethora of methods of treatment of hypoglycemic conditions comprising administering a peptide compound, wherein said peptide compound comprises a Gly at position 4 and Ala at position 18 wherein the other amino residues of the peptide are drawn from various combinations of amino acids defined in claim 1, each method being a special technical feature that is distinct from the other methods. Claims 32-34 will be examined only as they are drawn to the specific peptide compound elected. It is noted for Applicant's convenience that this is not a requirement for an election of species but rather a requirement to elect a specific method of treatment for examination. Applicant is required to identify and elect a single method for examination.

Group 5. Claim 35 is drawn to a plethora of peptide compounds different from those of Group 1 comprising a Gly at position 4 and Ala at position 18 wherein the other amino residues of the peptide are drawn from various combinations of amino acids defined in claim 35, each specific combination of amino acid residues being a special technical feature that is distinct from the other combinations. Claims 36-50 will be examined only as they are drawn to the specific peptide elected for examination. It is noted for Applicant's convenience that this is not a requirement for an election of species but rather a requirement to elect a specific peptide sequence for

examination. Applicant is required to identify and elect a single method for examination.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1 is drawn to a product and a process of use of said product.

Groups 2 and 5 do not form a single inventive concept with the invention of Group 1 because they are drawn to additional products.

Groups 3 and 4 do not form a single inventive concept with the invention of Group 1 because they are drawn to additional methods.

Accordingly, Groups 1-5 are not so linked as to form a single general inventive concept.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.
7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are

governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

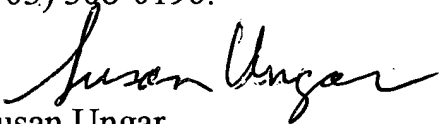
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

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(571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 308-0787. The fax phone number for this Art Unit is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Susan Ungar".

Susan Ungar

Primary Patent Examiner

September 18, 2005